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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,439	11/03/2003	Christine A. Franke	704787-2001	1516

7590 10/06/2006

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,439	<b>Applicant(s)</b> FRANKE ET AL.	
	<b>Examiner</b> Nancy T. Vogel	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/23/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-24 are pending in the case.

Receipt of the Information Disclosure Statement on 4/23/04 is acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-12 in the reply filed on 7/12/06 is acknowledged. The traversal is on the ground(s) that since the two groups have subject matter classified in the same class and subclass, they are related and therefore it would not be a burden for the examiner to examine all of the claims. This is not found persuasive because the subject matter of each group, while classified similarly, have divergent and different subject matter, being drawn to vectors have different structures (i.e. orfA and orfB in Group I, the nucleotides encoding amino acids 94 and 95 of the lacG gene in Group II). Therefore, the subject matter does not overlap and the search required for each Group is different. In addition, it is maintained that the search required for subject matter in the biotechnology area is not limited to the patent literature, but must be extended to the non-patent literature as well. Therefore, similar classification does not reduce the burden to the examiner for the search of the two Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/12/06.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a vector for the expression of foreign genes in any gram positive bacteria, comprising orfA and orfB. The specification has not disclosed the sequence (i.e. structure) of the molecules recited as "orFA and orfB", but rather describes them as open reading frames polynucleotides of unknown function which are isolated from *Streptococcus gordonii*, and which, when present on a vector and transformed into *Streptococcus gordonii*, provide a location for the stable integration of said vector into the chromosome via homologous recombination (see abstract,). The claim is a genus claim in terms of a

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vector for expression of foreign genes in any gram positive bacteria comprising orfA and orfB. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species of vectors encompassed by the claims as one of skill in the art cannot envision all the vectors for expression of genes in any gram positive hosts, comprising orfA and orfB. Since the orfA and orfB are taught in the specification as providing homologous regions for insertion of the vector into the chromosome, and since the specification further discloses that there are no sequence homologous to the *S. gordonii* orfA and orfB sequences in any gram positive microorganisms (page of the specification), it is clear that the specification has not taught vectors comprising orfA and orfB for use in any microorganism other than *Streptococcus gordonii*. Therefore, the specification does not describe the claimed vectors for expression of foreign genes in gram positive bacteria other than *S. gordonii*, in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "OrfA and OrfB" since the term "Orf" in the art is generally used to indicate an open reading frame, and therefore,

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the claim is confusing in that it cannot be determined whether applicants intend two defined, particular open reading frames, or any two open reading frames in general. Therefore, the claims fail to particularly point out and distinctly claim the intended subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanatani et al. ((J. of Fermentation and Bioengineering, 80, 4:394-399, 1995) (cited by applicants).

Kanatani et al. disclose a vector for expression of foreign genes in gram positive bacteria, which comprising orfA and orfB (see abstract). In absence of evidence to the contrary, it is considered that this plasmid would function in related gram positive bacterial host cells. There are sites would could function as an insertion site between OrfA and OrfB, including EcoRV (see Fig. 1, 3). The vector further comprises a selectable marker which is an antibiotic resistance gene, which is the erm (see pULA105E), Fig. 1).

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Claims 1-3, 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Oggioni et al. (Gene, 169, 1, 85-90) (cited by applicants).

Oggioni et al. disclose a plasmid for expression of foreign genes in gram positive cells, including *Streptococcus gordonii*, comprising OrfA and OrfB (see Fig. 1-3). The vector comprises a selectable marker which is *ermC*.

### ***Conclusion***

No claims are allowed.

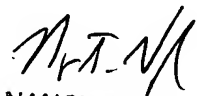
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV  
9/30/06

  
NANCY VOGEL  
PRIMARY EXAMINER